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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,338	07/11/2003	Jin-an Jiao	146392002520	8452

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
XIE, XIAOZHEN	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,338	JIAO ET AL.	
	Examiner	Art Unit	
	XIAOZHEN XIE	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,39,41-46,54,55,58,65 and 83-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37,39,41-46,54,55,58 and 65* is/are allowed.

6)☒ Claim(s) *83-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

The Information Disclosure Statement (IDS) filed on 19 August 2008 has been entered as indicated in the Advisory Action mailed on 17 October 2008. Applicant's amendment of the claims filed 19 August 2008 has been entered. Applicant's remarks filed 19 August 2008 are acknowledged.

Claims 1-36, 38, 40, 47-53, 56, 57, 59-64 and 66-82 are cancelled. Claims 83-96 have been added. Claims 37, 39, 41-46, 54, 55, 58, 65 and 83-96 are pending and under examination.

Claim Rejections Withdrawn

The rejection of claims 37, 39-46, 54-60, 65, 69-71 and 73-82 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in response to Applicant's cancellation of the claims.

The rejection of claim 69 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for introducing new matter of "an anti-tissue factor antibody derived from the amino acid sequence of SEQ ID NO:

2 or SEQ ID NO: 4, or fragment thereof", is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claims 69-71 and 73-82 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for variants of the antibody derived from the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 4, is withdrawn in response to Applicant's cancellation of the claims.

The rejections of claims 69, 71 and 75 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn in response to Applicant's cancellation of the claims.

The rejection of claims 69, 73 and 78-82 under 35 U.S.C. 102(b), as being anticipated by Edgington et al. (U. S. Patent NO: 5,223,427), is withdrawn in response to Applicant's cancellation of the claims.

The rejection of claims 74-77 under 35 U.S.C. 103(a) as being unpatentable over Edgington et al. (U. S. Patent NO: 5,223,427), in view of Queen et al. (U. S. Patent NO: 5,693,762), is withdrawn in response to Applicant's cancellation of the claims.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The newly added claims 83-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: *a method for reducing tissue factor (TF) levels to treat a tumor exhibiting TF expression, comprising administering to a human having the tumor a therapeutically effective amount of an anti-TF antibody that comprises six hypervariable regions which comprise sequences of SEQ ID NOs: 5-10 or a chimeric antibody of such anti-TF antibody,* does not reasonably provide enablement for administering the antibody to a human having any tumors. The basis of this rejection has been set forth in the previous office actions.

The newly added independent claim 83 recites "administering to a human having tumors a therapeutically effective amount of an anti-TF antibody". The claim language "a human having tumors" reads on patients having any types of tumors, rather than tumors exhibiting tissue factor expression. As stated previously, the specification is enabled for treating a patient having tumor cells that express TF on their surface, such as pancreatic, ovarian, or small lung cell carcinoma, however, the specification does not provide support for treating patients with any types of tumors, including those without TF expression on tumor cell surface. Amending the claim to "administering to a human having the tumors" would obviate the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 87, 88 and 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the invention as now claimed:

"The method of claim 83, wherein the antibody is a chimeric antibody and has at least 90% (claim 87) or 95% (claim 88) amino acid sequence identity to SEQ ID NO: 2 and SEQ ID NO: 4"; and

"The method of claim 83, wherein the antibody is encoded by a nucleic acid sequence that has at least 90% sequence identity to SEQ ID NO: 1 and a nucleic acid sequence that has at least 90% sequence identity to SEQ ID NO: 3".

Applicant's amendment, filed 19 August 2008, asserts that no new matter has been added and directs support for the newly added claims at various sections of the instant specification. However, these sections describe at least 90% or 95% sequence identity to one, two or three of the corresponding hypervariable regions of the light chain and heavy chain variable regions of the antibody (pp. 10, line 31 to pp. 11, line 14), or describe antibodies encoded by nucleic acids having 90% or 95% or more homology to SEQ ID NOs: 1 and/or 3 (pp. 12, 2nd full paragraph), or describe antibodies having 90% or 95% or more

homology to SEQ ID NOs: 2 and/or 4 (pp. 10, 2nd full paragraph). The instant claims, as depending from claim 83 which recites an antibody comprising six hypervariable regions having sequences of SEQ ID NOs: 5-10, are directed to the percentage homologies, i.e., 90% or 95%, outside of hypervariable regions (or CDRs). The instant specification as filed does not have support for these limitations, because the homologies described in the specification include the hypervariable regions. This is a new matter rejection.

Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06.

Conclusion

CLAIMS 37, 39, 41-46, 54, 55, 58 AND 65 ARE ALLOWED..

CLAIMS 83-96 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
January 16, 2009

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646